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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Mitsuo HONDA et al. : Docket No. 2005_0221A
Serial No. 10/524,586 : Group Art Unit **Not Yet Assigned**
Filed February 15, 2005 : Examiner **Not Yet Assigned**
RECOMBINATION BCG VACCINE

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☐ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No. _____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) ☐ the certification of paragraph 2 below is provided, **or**
(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and
the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Mitsuo HONDA et al.

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INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: May 12, 2005

ATTY DOCKET NO.
2005_0221ASERIAL NO.
10/524,586

MAY 12 2005

APPLICANT
Mitsuo HONDA et al.FILING DATE
February 15, 2005

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AJ						
	AK						
	AL						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

AM	L. Deml et al., "Multiple Effects of Codon Usage Optimization on Expression and Immunogenicity of DNA Candidate Vaccines Encoding the Human Immunodeficiency Virus Type I Gag Protein", Journal of Virology, Vol. 75, No. 22, pp. 10991-11001, November 2001.
AN	D. L. Narum et al., "Codon Optimization of Gene Fragments Encoding <i>Plasmodium falciparum</i> Merzoite Proteins Enhances DNA Vaccine Protein Expression and Immunogenicity in Mice", Infection and Immunity, Vol. 69, No. 12, pp. 7250-7253, December 2001.
AO	M. Uchijima et al., "Optimization of Codon Usage of Plasmid DNA Vaccine is Required for the Effective MHC Class I-Restricted T Cell Responses against an Intracellular Bacterium", The Journal of Immunology, Vol. 161, pp. 5594-5599, 1998.
AP	K. Matsuo et al., "Cloning and Expression of the <i>Mycobacterium bovis</i> BCG Gene for Extracellular α Antigen", Journal of Bacteriology, Vol. 170, No. 9, September 1988, pp. 3847-3854.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.